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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,513	03/26/2001	Therese Jourdiar	MBHB00-1282	3546

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EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/22/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,513

Applicant(s)

JOURDIER ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 10-15 are pending.

Response to Amendment

This is a response to the amendment, paper No. 8, filed 06/24/02. Claim 10 is amended. Claims 10-15 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claims 10-15 are still rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is still indefinite in that the metes and bonds of “an immunogen” and “a pathogen agent” are not defined. Applicants argue that the rejection is not based on the unclarity of the claims but the breadth of the claims. Therefore, the rejection should be withdrawn.

Applicants argument has been fully considered; however, it is not found persuasive because there are so many immunogen and pathogen in the art, the claim should point out which immunogen and pathogen are intended. There are so many pathogens in the art, which are able to spread the infection through the rectal, genital and/urinary mucous membranes, are hepatitis B virus intended?

Claims 10-15 are still rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01.

Applicants argue that there are no elements in the claims that require connection by recitation of a particular kind of immunogen; recitation of “immunogen” is sufficient to connect administration and the elicitation of a response. Applicants’ argument has been fully considered; however, it is not found persuasive because the claimed invention is deal with a method, however; the method cited in the claims does not teach what kind of antigen is intended and what

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kind of the immune procedure is followed for each different kind of the pathogens as claimed in the claims 14. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112

Claims 10-15 are still rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for sensitizing the B lymphocytes isolated from the located lymph nodes, such as internal or external iliac lymph nodes, inguinal lymph nodes in an ex vivo experiments and getting some secreted IgA in the rectal, genital and/or urinary wash by injecting an immunogenic composition comprising the HIV gp120 and gp160 intramuscularly into the thigh of mice, does not reasonably provide enablement for inducing similar immune response in human by injecting any or all immunogen for any or all pathogen agents as listed in claims 14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants asserted that scope of the claims does not comprise all immunogens of all pathogen or pathogens recited in claims 14. Rather, the scope of the claims is imitated to “an immunogen of a pathogenic agent having a gateway into the rectal, genital and/or urinary mucous membranes.” The office action has not alleged that this scope has not been enabled.

Applicants’ argument has been fully considered; however, it has not found persuasive because the immunogen of a pathogen include any or all immunogen of a pathogen including the immunogen of a pathogen listed in claim 14.

Applicants further argue that the two examples cited by the office in the previous office action is not the antigen that having a gateway into the rectal, genital and/or urinary mucous, therefore, it is not proper for indicating the filed of unpredictability of inducing a systematic or local immune response by injecting an immunogen intramuscularly.

Applicants’ argument has been respectfully considered; however, it is not found persuasive because the references cited in the previous office action, although the immunogen does not have the gateway into the rectal, genital and/or urinary mucous, they teach that it is unpredictable for regional injection of an immunogen although nearby its original infection route, is may not able to induce the regional or systematic immune response.

Especially considering the imitated disclosure of the specification comparison with the broad scope of the claims, it is still concluded that undue experimentation would be required for making and using the claimed invention. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 10-14 are still rejected under 35 U.S.C. 102(e) as being anticipated by Morrow et al. (US Patent No. 6,063,384A).

Claims 10-14 are still rejected under 35 U.S.C. 102(e) as being anticipated by Whittle et al. (US Patent NO. 6,123,948A).

Claims 10-15 are still rejected under 35 U.S.C. 102(e) as being anticipated by Krieg et al. (US Patent NO. 6,339,068B1).

Claims 10-15 are still rejected under 35 U.S.C. 102(a) as being anticipated by Cohen et al. (US Patent No. 5,654,174A, August 5, 1997).

Claims 10-15 are still rejected under 35 U.S.C. 102(b) as being anticipated by Carrano et al. (WO 95/26718A1).

Applicants argue that no of the references cited teach the thigh as the site of administration. The cited art, therefore, simply cannot anticipate the claimed invention. The rejection should be withdrawn.

Applicants' argument has been fully considered, however, it is not found persuasive because every of the artisan in the art know that the thigh is the muscular site that is the site for an intramuscularly injection of an immunogen and it has been practically used clinically before. Therefore, all the rejections are maintained.

Claim Rejections - 35 USC § 103

Claims 10-15 are still rejected under 35 U.S.C. 103(a) as being unpatentable over McBride et al. (Vaccine 1988, Vol. 6, pp. 414-418) and Lehner et al. (J. Immunol. 1994, Vol. 15, pp. 1858-1868).

Applicants argue that neither McBride et al. nor Lenher et al. teach or suggest administration to the human thigh to induce a local response in the rectal, genital, and/or urinary mucosal tissue. Applicants further asserted office ha merely presumed that administration "near"

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the internal iliac nodes is sufficient to render obvious the presently claimed invention. Therefore, the presently claimed invention cannot be obvious. The rejection should be withdrawn.

Applicants' argument has been respectfully considered; however, it is not found persuasive because McBride et al. do disclose an importance of the vaccine injected subcutaneous in the distant, is capable of generating memory mucosal immunity in the guinea-pig vaginal mucous. They also suggested that since serum antibody does not prevent recurrent infection, the production of local immunity, mediated by both T and B cells, would be important aspects to investigate in any potential herpes vaccine. Lehner et al. teach a protective mucosal immunity is elicited by injecting the vaccine consisting of rSIV protein p27 administered in the proximity of the internal iliac lymph nodes. The secretory IgG and IgA abs to p27 Ag were elicited in the vaginal, male urethral, rectal and seminal fluids, urine and serum. They conclude that generating secretory IgA and IgG Abs at the mucosal surface, and T and B cell immunity in regional draining lymph nodes, spleen and circulation may prevent the virus through the mucous, dissemination of virus, and the formation of a latent reservoir of infection (See entire document). Because the thigh is the iliac lymph node is the lymph nodes collect all the lymphocinesia fluid in the thigh, therefore, the injection of the immunogen though the thigh will be through the iliac lymph nodes and get the IgG secreted through the mucosal nearby.

As there are no unexpected results have been provided, the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


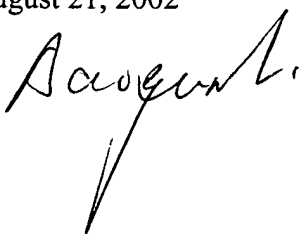
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

August 21, 2002



ALI R. SALIMI
PRIMARY EXAMINER